Massachusetts Department of Public Health

State Laboratory Institute

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Packaging and Shipping Clinical Specimens

Laboratories routinely package and ship clinical specimens by transportation carriers that are regulated by multiple federal and international regulations. In addition, the International Air Transport Association (IATA) regulations require that packaging documentation for specimens that are sent by air must include a signature of a person trained and certified as knowledgeable in the IATA regulations *(www.iata.org and www.dgitraining.com).* This article poses a series of questions to aid you in assessing training needs for current packaging and shipping requirements.

Can you correctly classify a clinical specimen as diagnostic or as an infectious substance according to applicable U.S. and International regulations? In order to select the correct type of packaging material, appropriate labels and acceptable transportation carrier, you must be able to identify your specimen according to these defined categories. A diagnostic specimen is a clinical specimen sent for routine screening or initial diagnosis other than the presence of a pathogen, and one that is not expected to contain an infectious substance. Examples of diagnostic specimens are a blood sample for routine lead analysis, a filter paper blood sample for newborn screening and a serum specimen for cholesterol testing. An infectious substance is a clinical specimen submitted for initial or confirmatory testing of a suspected pathogen or a specimen that is known to contain an animal or human pathogen. Examples of infectious substances are a sputum sample for *M. tuberculosis* testing, a culture that contains or is suspected of containing a pathogen and a blood sample from a person with an active or chronic infection, e.g., hepatitis B. International regulations mandate that the exterior of the outer packaging used to ship samples be clearly marked and labeled, either "Diagnostic Specimens" or "Infectious Substances" and that the package must be marked as meeting UN specifications for shipping infectious substances, Class 6.2. These regulations are becoming more universal and are considered an industry standard.

Are you knowledgeable in the regulations that should be followed for different shipping means? The following are examples of some of the carrier specific requirements and operator variations to the regulations. Specimens sent by mail must be packaged according to the U.S. Postal Service (USPS) Regulations found in the Domestic Mail Manual, (DDM), Regulation CO23.8.0, for Infectious Substances. The postal service has designed a document providing supplemental information and guidance based on the DDM entitled, "Hazardous, Restricted, and Perishable Mail". This document, also known as Publication 52 dated July of 1999, contains specific packaging instructions in appendix C for diagnostic specimens (6C) and infectious substances (6B), and is available through your local post office *(www.usps.gov).*

Specimens sent by commercial overnight carriers, e.g., UPS, FedEx and DHL, must be packaged in accordance with the IATA Dangerous Goods Regulations. Dangerous goods include 9 classes of materials such as explosives (Class 1), flammable liquids (Class 3) and toxic and infectious substances (Class 6). Usually, clinical laboratories are concerned with infectious substances (Division 6.2). However, many carriers will transport only diagnostic specimens, and not infectious substances. The IATA regulations can be found in the *International Air Transport Association, Dangerous Goods Regulations, 41st Edition, effective January 1, 2000.*

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Laboratory Surveillance of West Nile Virus Infections

by SLI Arbovirus Surveillance Program

The introduction of West Nile Virus (WNV) in the northeastern United States during the summer and fall of 1999 raises the possibility that WNV may persist in the environment and spread to other geographical areas. The State Laboratory Institute (SLI) will conduct laboratory-based surveillance for WNV to aid prevention and control efforts to limit the potential public health impact. The components of this laboratory-based surveillance include 1) collection, sorting by species and testing mosquitoes to detect virus and help identify potential vectors, 2) testing birds to monitor for the presence and spread of WNV, and testing horses and other veterinary specimens with suspect WNV infection, and 3) testing human specimens from suspect cases of viral encephalitis and aseptic meningitis. The SLI will follow Centers for Disease Control and Prevention (CDC) protocols in testing for WNV. Training and reagents are being provided by the CDC.

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Packaging and Shipping Clinical Specimens

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UPS will transport diagnostic specimens, but not infectious substances, if they are packaged in accordance with the Department of Transportation (DOT), Division 6.2. Hazardous Materials Regulations for Infectious Substances *(hazmat.dot.gov and www.ups.com)*. FedEx will transport diagnostic samples for delivery packaged according to IATA regulations (PI-650), and infectious substances in Risk Group 2 and Risk Group 3 packaged according to IATA PI-602. Corporate policy is subject to change, and you should contact a carrier to determine their current guidelines.

DOT and/or CDC regulations apply to private clinical and hospital laboratory couriers. Therefore, all specimens transported must follow packaging protocol that minimally consists of a watertight primary (specimen) container with a screw cap or stopper secured with parafilm, etc., liquid and shock absorbent packing, a watertight secondary container and an outer container. (See precaution guidelines, shipping at *www.cdc.gov* or regulations at *www.saftpak.com*).

Are you knowledgeable in the regulations that pertain to select agents? The U.S. Centers for Disease Control Regulations (42CFR Part 72) define a class of special infectious substances that must be tracked to assure their safe arrival. These infectious substances, which are listed in Appendix A of 42 CFR Part 72, present a potentially high risk of infection and/or death to persons exposed to them. In addition to the additional requirements for prior notification and tracking of the shipment, these microbiological agents and toxins can be transported only between parties that are registered under the Select Agent rule. Although laboratories licensed under CLIA are exempt from the registration process of the Select Agent Rule, they must follow these regulations for safe transport of specimens including marking the exterior of the outer packaging with the complete name and telephone number of a person responsible for each shipment. When transporting infectious substances classified as select agents, you must notify the consignee and operator of the shipment to ensure expeditious transport and monitoring of the substance in transit.

The safe packaging and shipping of specimens is important to the goal of timely, accurate test results and can be assured only if the detailed regulatory requirements are fully understood. Training in the regulations will provide you with the knowledge and references needed to stay abreast of the latest information in this frequently changing area. And you must have a demonstrated knowledge of IATA regulations by satisfactorily passing a written exam in order to ship diagnostic specimens and infectious substances by air.

Training

Two or three day training programs for the packaging and shipping of all classes of dangerous goods are offered by an increasing number of shippers and commercial training companies. If you do not have staff trained at present, you can receive information on packaging from several sources including the U.S. Postal Service, large commercial overnight courier services, suppliers of UN approved packaging and the U.S. Public Health Service's Centers for Disease Control and Prevention.

The State Laboratory Institute (SLI) recently developed a one-half day training program on the requirements for packaging and shipping clinical specimens specifically for clinical laboratory professionals. For information on this course and how to register for a training session, contact Garry Greer, State Training Coordinator, SLI at 617-983-6608 or e-mail: *garry.greer@state.ma.us*. SLI plans to offer the one-half day training program several times during the coming year and we look forward to your participation. If you have questions concerning packaging and shipping, you can contact Phyllis Madigan at 617-983-6656 or e-mail: *phyllis.madigan@state.ma.us*.

Laboratory Surveillance of West Nile Virus Infections

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Serology

Antibody to WNV can be detected in serum specimens using IgM and IgG enzyme-linked immunosorbent assays. Neutralization assays can also be conducted on these samples to identify virus-specific antibody responses. Serum specimens may be held at +4°C prior to shipment and transported at ambient temperature.

Virus isolation, detection and identification

Cell lines at SLI (VERO and BHK-21) can be used to isolate WNV. Appropriate human or equine specimens for viral isolation include cerebrospinal fluid (CSF), and brain biopsy or autopsy tissue specimens. Specimens for isolation should be sent on wet ice by courier to SLI on the day of collection. Specimens not sent within 24 hours should be frozen at -70°C and shipped on dry ice. (N.B. Refer to article in this issue or International Air Transport Association (IATA) Guidelines for instructions on appropriate packaging and shipping). Virus is detected by observing cytotoxicity in cell cultures followed by identification of virus using an indirect fluorescent antibody (IFA) assay. Reverse transcription-polymerase chain reaction (RT-PCR) can also be used to detect WNV in tissue specimens.

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Grants, Projects & Publications —

Public Health Laboratory Fellowships Available

Applications are now being accepted for the Emerging Infectious Disease (EID) Fellowship Program and must be received at APHL in Washington, D.C. by March 31, 2000. The program, sponsored by the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC), expects to place 20 EID Fellows at State Public Health Laboratories and CDC for the upcoming fellowship period. There are two fellowship categories: the Post-Doctoral Laboratory Research Fellowship, and the Advanced Laboratory Training Fellowship for baccalaureate and masters level candidates. Having hosted two very successful fellows in the past, SLI will again apply as a Host State Laboratory for both training and research positions for the next fellowship period, which runs from September 2000 through August 2001.

APHL/CDC additionally offers an EID International Laboratory Fellowship for non-U.S. citizen doctoral level scientists, and an Environmental Health Laboratory Sciences (EHLS) Post-Doctoral Fellowship Program. Please call for more information and application deadlines on these programs.

If you are interested in projects at SLI, we encourage you to contact the State Laboratory Director, Ralph Timperi, at 617-983-6201or the Fellowship Site Facilitator, Marcia Stowell, at 617-983-6283. Application forms and information are available through the Internet: *http://www.aphl.org*. An application packet may be obtained by calling APHL at 202-822-5227.

Laboratory Surveillance of West Nile Virus Infections

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Clinical Specimens

Clinical laboratories can assist SLI by forwarding appropriate human specimens for laboratory diagnosis of WNV infections. Clinical specimens from suspect cases may be handled using standard laboratory safety precautions for serum and tissue specimens (BSL-2). However, WNV is classified as an agent that requires BSL-3 containment for certain procedures, such as virus isolation. Individuals who work with viral cultures for diagnostic and research purposes should confirm with their institutional safety official that their laboratory areas meet safety guidelines for BSL-3. (See *Biosafety in Microbiological and Biomedical Laboratories*, CDC and NIH, Fourth Edition, May 1999).

Field Specimens

Laboratory-based surveillance will include collection and testing of appropriate field specimens to monitor WNV in the environment. This surveillance will provide information for public health and environmental programs to advise the public on effective means to prevent human disease and control potential mosquito vectors. SLI will supplement its Arbovirus Surveillance Program, which monitors for eastern equine encephalitis virus (EEEV), to include testing for WNV. The suspect vectors of WNV are species of the *Culex* genus, which breeds in discreet areas without the need for high water levels. These species are readily found in sites such as sewers and standing, muddy water in urban areas. Mosquitoes will be collected from appropriate sites and after species identification, processed in pools of up to 50. Extracts of the specimens will be inoculated onto VERO and BHK-21 cell cultures. Supernatants from cell cultures that exhibit plaques indicating cytotoxicity will be tested by IFA with antibody for WNV. Samples will also be tested by RT-PCR.

The SLI Arbovirus Surveillance Program will also monitor and test specimens from birds that may be infected with WNV, since information derived from these specimens will aid in directing further surveillance and control efforts. SLI will accept avian samples for WNV analysis based upon the number, location, and condition of the birds. Tissue samples from submitted birds will be tested for WNV by plaque assay and RT-PCR. Additionally, the surveillance program will monitor crow roosts throughout the state and bleed trapped birds prior to their release. Serum samples from birds will also be tested for antibody to WNV by neutralization assay.

Questions regarding suspect human and veterinary cases or avian surveillance should be directed to (617) 983-6800. Specific questions about laboratory testing should be directed to (617) 983-6383 or (617) 983-6796. Throughout the season, additional information can be found at the Epidemiology and Immunization Division website at *http://www.state.ma.us/dph/cdc/epiimm2.htm* and at the Infectious Disease Laboratories Division website at *http://www.state.ma.us/dph/bls/viro.htm*.

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for the electronic version of this newsletter and other information about the State Laboratory Institute: www.state.ma.us/dph/bls.

Laboratory Training Activities

The Role of Clinical Laboratorians and Infection Control Practitioners in Surveillance and Reporting of Infectious Disease - Concord, NH, March 30 & Hartford, CT, March 31: Full-day workshop. Fee $40. Call (617) 983-6285.

Expert Witness Workshop for the Laboratorian - State Laboratory Institute, Boston, MA, June 5: Full-day workshop. Fee $75. Call (617) 983-6285.

Public Health Teleconference Series - State Laboratory Institute, Boston, MA: Packaging & Shipping of Infectious Materials, March 14; Public Health & Clinical Laboratories - Opportunities and Challenges Presented by Managed Care, April 11. Fee $35 per site per program. Call (617) 983-6285.

State Laboratory Training Coordinator, *Garry R. Greer, BS, (617) 983-6608, E-mail: garry.greer@state.ma.us.*
For a list of NLTN courses in your area sign on to the Web at http://www.cdc.gov/phppo/dls/nltn.htm.

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